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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478
28596	7590	12/12/2005		
GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206				
			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/499,423

Applicant(s)

CAMPBELL ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-33,35,42-44,46-66,74-77,82-88 and 91-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-33,35,42-44,46-66,74-77,82-88 and 91-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/05 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 86-88, 91, 95-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldfarb (6436135). Goldfarb discloses a tube of PTFE (col. 3, lines 40-55) that is fully capable of having its circumference increase with blood pressure application. The prosthesis is for use as a vascular graft, col. 1, lines 3-5. The graft is fully capable of being adapted for use as an endoluminal graft. The tube has a wall thickness about 0.25mm, col. 7, lines 9, 10. Regarding claim 91, the use of "minimal recoil" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. The examiner asserts that the graft can be construed to have "minimal" recoil since it can be construed that any amount less than 50% is minimal.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,9-17, 19-31,33,35,42-44,46-66,74-77,82-88,91-97 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shannon et al. (5641373). Shannon et al. disclose each and every structural element of the claimed tube set forth in claims 1,33,86. Shannon disclose an article comprising a porous polytetrafluoroethylene tube base and is covered by one or more layers of porous PTFE material or film, (col. 2, lines 21-24) but is silent about the method of processing the tube to have the tube circumference remain "substantially unchanged" or limit recoil. The claimed phrase "circumference of the tube remains "substantially unchanged" or has minimal recoil" is being treated as a product by process limitation; that is, that the ptfe tube is made by an analogous process. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Shannon fails to disclose the process used to make the tube with minimal recoil, it appears that the product in the Shannon reference would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made from the same material (see page 2 of response or remarks in amendment of 9/26/05). Additionally the use of "remains substantially unchanged" in

claims 1,33 is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Shannon also discloses the device has a microstructure of nodes and fibrils, col. 1, lines 19-30. The wall thickness has a measurement of about 0.1 mm and less than 0.25mm, see col. 16, lines 57,58. The graft can be anchored via a stent, col. 11, lines 8-14 and can also be sutured, line 55. Since a stent can be used with the ptfe tube, it can be said that the device has "minimal recoil" or "remains substantially unchanged" since the stent will cause the tube to have no recoil. The tube is fully capable of having a second circumference 100% greater than the first or initial circumference since the tube is made of the same material and has the same thickness. Regarding claims 17 and 31, since the graft is inherently capable of expanding to a second circumference, it is fully capable of having a tapered profile upon expansion in a tapered vessel.

However, in the alternative Shannon is silent with respect to any percentages of recoil as in claims 11-13,42-44,91-94 for the tube once expanded. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a ptfe tube having a range between 14,10 or 7% or less, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 18,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. '373 in view of Hughes et al. (4728328). Shannon et al. is explained supra. However, Shannon does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It

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would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Shannon in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb '135. Goldfarb is explained supra. However, Goldfarb fails to disclose the minimal recoil is 14% or less. It would have been an obvious matter of design choice to modify the minimum recoil, since applicant has not disclosed that using any particular percentage provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the recoil taught by Goldfarb or the claimed 14% or less in claim(s) 92 because both tubes perform the same function of providing a graft to permit blood flow through them. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a ptfe tube having a range between 10% or less and 7% or less, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 9/26/05 have been fully considered but they are not persuasive. In response to applicant's argument that Goldfarb fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., some structural difference in the tube not defined or clear from the different

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process of making that is stated) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that the Goldfarb tube has a "large" amount of recoil, and states that the Goldfarb tube has a 15.4% recoil and disclose a tube of 14% recoil or less. It can be construed that 14% touches the 15.4% amount. When the prior art discloses a range, which **touches**, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. Since these amounts are so close, it can be said that Goldfarb anticipates the claims and is definitely obvious with respect to the claimed recoil of 14%. Regarding the Shannon reference, it is the Examiner's position that the claims do not clearly set for the structural features of the tube with respect to uncontrollable external forces. Applicant argues that the Shannon tube does not have a second circumference at least 100% greater than the first circumference because it is made differently. If the product in the product-by-process claim is the same as a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since, Applicant has failed to indicate any structural difference in the prior art material from the claimed invention, it is assumed the Shannon tube has a second circumference that is 100% greater than the first. Applicant has not shown any evidence that the Shannon tube cannot have a second circumference 100% greater than the first other than pointing out differences in steps of manufacturing the tubes.

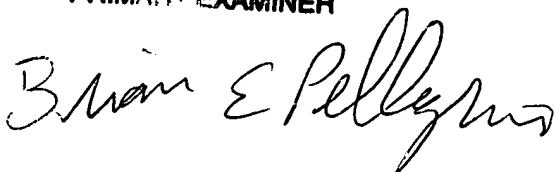
The Shannon tube was not tested to prove the tube is not capable of expanding 100%.
Thus, the Examiner is not persuaded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style with a large, stylized "B" and "P".